

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/9/09 has been entered.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,2,5-7,15-17,21-23,28,29,31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (6071305) in view of Tower et al. (EP 105460) per St. Germain (5836966). Brown et al. disclose (Fig. 1) a stent **11** having a longitudinal hollow core section **20** extending along a longitudinal axis of the tubular member (Fig. 6) within the stent portion and a multiplicity of pores **28** providing fluid communication between the hollow core section and the external environment. It can also be seen there is a therapeutic agent **23** contained in the hollow core section wherein the therapeutic agent is configured to be eluted from the one or more hollow core sections into the vessel **24** through the multiplicity of pores after implantation of the stent within the

vessel. Brown et al. disclose other stent configurations are within the scope of the invention, col. 7, lines 34-38. However, Brown fails to illustrate another embodiment such as one with a plurality of separate circumferential rings each having a plurality of upper peaks and lower peaks in which the lower peaks of one circumferential ring are coupled to the upper peaks of an adjacent circumferential ring. Tower et al. teach (Fig. 2) a stent where individual circumferential rings **21** are coupled together at welds **40** where a lower peak of a ring is coupled to the upper peak of an adjacent ring. Tower also teaches the ring formation allows for great flexibility, Paragraph 18. It is noted that St. Germain teaches that various stent designs are interchangeable depending on the vessel requirements (col. 2) and can include circumferential rings with peaks and valleys linked or coupled together, Fig. 9. Thus, it would have been obvious to one of ordinary skill in the art to use separate circumferential rings of peaks and valleys coupled together as taught by Tower for the stent of Brown et al. per the teaching of St. Germain in order to provide a drug eluting stent that provides the optimal support necessary to the vessel being treated. Regarding claims 5,22 it can be interpreted that adjacent pores have a distance with respect to one another and non-adjacent pores are at a different distance with respect to one another. With respect to claims 6,21 Brown discloses that stents have the pores circumferentially about the exterior surface of the tubular member, Figs. 17,18. Regarding claim 7, Brown et al. also discloses that the pore size and number can be varied to control elution rate, col. 9, lines 30,31. With respect to claims 15,16,30,32 and the method of making, Tower discloses the steps of forming three or more separate rings (Fig. 3) and coupling the peaks and valleys of the

rings together to form a stent which thus can be said to have proximal ends since forming a ring from a hollow wire material has to have ends, see paragraphs 27-29. Regarding claim 17, Brown et al. disclose the tubular member stent can be a shape memory alloy, col. 5, lines 41-44, col. 7, lines 14-19. With respect to claim 28, Brown discloses the stent is balloon expandable, col. 7, lines 31-33. Regarding claims 29,31 Brown et al. disclose that bioabsorbable polymers (col. 8, lines 62-65, col. 9, line 1, col. 10, lines 19-21) are used as means for controlling release from the channel into the lumen of the patient.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. '305 in view of Tower et al. (EP 105460) per St. Germain '966 as applied to claim 1 above, and further in view of Harry (2002/0038146). Brown et al. as modified by Tower per St. Germain is explained *supra*. Brown does disclose the pores can be any type of opening or shape, col. 6, lines 15-18. However, Brown in view of Tower per St. Germain fail to disclose the pores vary in size or shape with respect to one another. Harry teaches (Figs. 2,3) pores varying in size on the stent. Harry also teaches (Fig. 8) pores that vary in shape on the stent. It would have been obvious to one of ordinary skill in the art to vary the size or shape of the pores as taught by Harry with the stent of Brown as modified with Tower per St. Germain to provide different amounts of therapeutic material released from the stent.

Claims 26,27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. '305 in view of Tower et al. (EP 105460) per St. Germain '966 as applied to claim 1 above, and further in view of Dang (6758859). Brown et al. as modified by

Tower per St. Germain is explained *supra*. Brown does disclose (Figs. 9,10) multiple or first and second therapeutic agents **23,25** can be used, col. 11, lines 1-13. However, Brown in view of Tower per St. Germain fail to disclose the first and second rings have the different agents. Dang teaches one ring can have a first therapeutic agent and second ring can have a second therapeutic agent, col. 6, lines 9-11. It would have been obvious to one of ordinary skill in the art to place different agents on different rings as taught by Dang with the stent of Brown as modified with Tower per St. Germain to provide different therapeutic material to be released from the stent to different vessel sites, such as one area of the stent may cover a lesion or plaque while another may not be placed in the vessel to cover it thus not requiring a drug or a different drug depending on the requirements, see Dang, col. 6, lines 14-17.

Response to Arguments

Applicant's arguments with respect to claims 1,15,23 have been considered but are moot in view of the new ground(s) of rejection. Applicant mentioned Brown does not teach the ring formation as claimed. However, it is noted that Brown does state other stent configurations are within the scope of the invention as mentioned above in the action. It is also noteworthy that St. Germain illustrates other variations of stents that one of ordinary skill can consider in using when contemplating what configuration to use to deliver the drug in a hollow core section of a stent disclosed by Brown. Thus, it would

have been obvious to use multiple rings as taught by Tower as the formation of the design.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-F (7:30am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738